

At some point in 2004, and no later than October 2004, Plaintiff was diagnosed with gynecomastia -- the development of glandular breast tissue in males. Plaintiff estimates that each of his breasts grew to be larger than a tennis ball. Plaintiff's doctor informed him that surgery was the only treatment.

In October 2004, Plaintiff was 65 inches tall and weighed 166 pounds, which his medical record describes as overweight. A contemporaneous test of Plaintiff found that his prolactin levels were normal. Between March 2005 and the Fall of 2005, he was again prescribed Risperdal for his behavioral issues. A physical examination of Plaintiff in June 2005 found that he was 68 inches tall, weighed 187 pounds and had gynecomastia.

During high school and for a year thereafter, Plaintiff used marijuana. In either 2013 or 2014, a court ordered Plaintiff to receive "assisted outpatient treatment." As part of the treatment, Plaintiff was prescribed Risperdal among other drugs. In June 2016, Plaintiff was 72 inches tall, weighed 189 pounds and had gynecomastia. Even though he had lost twenty pounds since 2006, his breasts were the same size they were when he first developed gynecomastia in 2004.

B. Risperdal's Labeling

In 1993, the FDA approved Risperdal for adult use. Risperdal's label contained the following in its "PRECAUTIONS" section:

Hyperprolactinemia: As with other drugs that antagonize dopamine D₂ receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. . . . Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds, the clinical significance of elevated serum prolactin levels is unknown for most patients.

The 1993 label also stated that the "[s]afety and effectiveness in children have not been established."

In October 2006, Defendant revised the “PRECAUTIONS” section of the Risperdal label. The new label stated:

Hyperprolactinemia: As with other drugs that antagonize dopamine D₂ receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. . . . Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.

. . .

Pediatric Use: The safety and effectiveness of [Risperdal] in pediatric patients with schizophrenia or bipolar mania have not been established.

. . .

Hyperprolactinemia, Growth, and Sexual Maturation: Risperidone has been shown to elevate prolactin levels in children and adolescents as well as adults. . . . In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorders treated with risperidone, . . . gynecomastia was reported in 2.3% of risperidone-treated patients.

C. Plaintiff’s Proposed Medical Expert

Plaintiff’s proposed medical expert is Dr. Barry Bercu, a pediatric endocrinologist. According to Dr. Bercu’s report and testimony, (1) Plaintiff has gynecomastia, (2) the medical literature reflects that Risperdal can cause gynecomastia and (3) his opinion, to a reasonable degree of medical certainty, is that Risperdal was a substantial contributing factor to Plaintiff’s gynecomastia. Dr. Bercu opined that other potential causes of gynecomastia -- puberty, obesity and marijuana use -- either did not cause or were not the only cause of Plaintiff’s gynecomastia. His opinions were based upon his review of Plaintiff’s medical records, his deposition testimony, medical studies and pictures and measurements of Plaintiff’s breast that Dr. Bercu reviewed after preparing his report.

D. Procedural History

In August 2014, Plaintiff filed suit in state court against Defendant and other parties. Defendant removed this case to federal court based on diversity jurisdiction. The Second

Amended Complaint, the operative complaint, alleges 11 causes of action against Janssen arising under New York law: negligence, strict products liability, manufacturing defect, failure to warn, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, fraud and deceit and violation of New York General Business Law §§ 349 & 350. Janssen, the only remaining Defendant, moves to preclude the expert testimony of Dr. Bercu pursuant to Federal Rule of Evidence 702 and moves for summary judgment on all claims.

II. MOTION TO PRECLUDE PLAINTIFF'S EXPERT

Defendant argues that Dr. Bercu's testimony must be precluded and, as a result, it is entitled to summary judgment on all claims because Plaintiff lacks admissible expert testimony to support his allegation that Risperdal caused his gynecomastia. This argument is rejected.

Federal Rule of Evidence 702 governs the admissibility of expert testimony. The rule provides that:

[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if[] (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Courts play a “gatekeeping” role within the Rule 702 framework and are “charged with ‘the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.’” *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993)); accord *In re Pfizer Inc. Sec. Litig.*, 819 F.3d 642, 658 (2d Cir. 2016). Examination of an expert's analysis should be “rigorous,” but “[a] minor flaw in an expert’s reasoning or a slight

modification of an otherwise reliable method will not render an expert's opinion *per se* inadmissible.” *Amorgianos*, 303 F.3d at 267. The party proffering the expert bears the burden of proof on the admissibility of his expert’s testimony. *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 253 (2d Cir. 2016).

To prevail on a products liability claim under New York law, a plaintiff must show that the product was “a substantial factor in bringing about [the plaintiff’s] injury or damages.” *Doomes v. Best Transit Corp.*, 958 N.E.2d 1183, 1191 (N.Y. 2011) (quoting *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983)); *see Caccese v. Liebherr Container Cranes, Ltd.*, 53 N.Y.S.3d 59, 61 (2d Dep’t 2017) (“Whether an action is pleaded in strict products liability, breach of warranty, or negligence, the plaintiffs must prove that the alleged defect is a substantial cause of the events which produced the injury.” (internal quotation marks omitted)). Causation requires proof of both general and specific causation. *See Cornell v. 360 W. 51st St. Realty, LLC*, 9 N.E.3d 884, 892 (N.Y. 2014). General causation concerns whether exposure to the product is capable of causing the type of injury that the plaintiff alleges; specific causation concerns whether, in the particular circumstance, the plaintiff’s exposure actually caused the alleged injury. *Id.*; *accord Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 251 n.1 (2d Cir. 2005).

Dr. Bercu’s testimony is admissible under Federal Rule of Evidence 702 and raises a triable issue of fact as to whether Risperdal was a substantial factor in causing Plaintiff’s gynecomastia. Dr. Bercu is a witness “qualified as an expert by knowledge, skill, experience, training, or education,” Fed. R. Evid. 702, and in this case, the strength of these qualifications “provides circumstantial evidence of reliability,” *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 179 (S.D.N.Y. 2009). Between 1974 through 1977, he trained as a fellow in pediatric

endocrinology at Massachusetts General Hospital and Harvard Medical School. Between 1977 and 1984, at the National Institute of Child Health, he both created the pediatric endocrine training program and headed the Pediatric Endocrine Unit. From 1984 to 2011, he was a professor at the University of South Florida College of Medicine. He also had a clinic practice in pediatric endocrinology from 1977 through 2011 and diagnosed dozens of children with gynecomastia. Dr. Bercu currently consults for the Social Security Administration and reviews pediatric medical records to assist with benefit determinations.

Dr. Bercu's testimony regarding general causation -- that Risperdal is capable of causing gynecomastia -- is sufficiently reliable. He reviewed six medical studies that addressed causes of gynecomastia, gynecomastia in adolescents or the relationship between gynecomastia and drugs. One study reviewed the FDA's Adverse Event Reporting database, which, according to Dr. Bercu, "clearly demonstrated the association with Risperdal and gynecomastia." The study found that the frequency of gynecomastia was "many times higher with risperidone than with the other antipsychotics." Dr. Bercu explained that although the study does not carry the same persuasive force as a placebo-controlled trial, it was still trustworthy based on the "very large" dataset it analyzed. *See id.* at 184 ("[A] large number of case reports adds greater weight to the reliability of an opinion on causation . . ."). Another study on which he relied is an "evidence-based review" of "drug-gynecomastia associations" that concludes there was a "fair quality of evidence for [Risperdal's] association with gynecomastia." These articles are corroborated by more recent studies regarding drug-induced gynecomastia. Indeed, Defendant's own expert acknowledges that "the risk for gynecomastia in patients treated with risperidone is greater than the general population with [the] risk being estimated to be increased up to 5-fold in those less than 18 years of age."

Dr. Bercu's testimony regarding specific causation -- that Risperdal was a cause of Plaintiff's gynecomastia -- is also sufficiently reliable. Dr. Bercu's opinion was based on a differential diagnosis, which is "a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes." *Ruggiero*, 424 F.3d at 254 (internal quotation marks omitted). "While an expert need not rule out every potential cause in order to satisfy *Daubert*, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." *DeRienzo v. Metro. Transp. Auth.*, 694 F. Supp. 2d 229, 236 (S.D.N.Y. 2010).

While Dr. Bercu noted that other possible causes of gynecomastia include puberty, obesity and marijuana, he reasonably dismissed them as a cause or the only cause in this case. Dr. Bercu testified that, unlike the typical case of pubertal gynecomastia, Plaintiff's breasts are much larger and did not become smaller within a few years. He dismissed marijuana as the cause because Plaintiff's marijuana use occurred years after he developed gynecomastia. If a patient had obesity-induced gynecomastia, Dr. Bercu explained that the patient's breasts would decrease in size if he lost weight. Plaintiff's gynecomastia, however, remained "very significant" even after he lost twenty pounds. Dr. Bercu also averred that, although it is possible that obesity may have been *a cause* of Plaintiff's gynecomastia, his opinion was that, to a reasonable degree of medical certainty, Plaintiff's Risperdal use was a substantial contributing factor. He explained that his opinion as to the causal connection between Risperdal and Plaintiff's gynecomastia was based on the medical studies discussed above, Plaintiff's medical records from 2004 to 2014, the pictures and measurements of Plaintiff's gynecomastia and the temporal proximity between his first exposure to Risperdal and his development of

gynecomastia. Dr. Bercu's testimony satisfies Federal Rule of Evidence 702. *See, e.g., Figueroa v. Bos. Sci. Corp.*, 254 F. Supp. 2d 361, 367 (S.D.N.Y. 2003) (Chin, J.) (admitting medical expert opinion based on review of depositions, medical records, scientific literature and temporal connection between an incident and the injury).

Defendant's arguments to the contrary are unavailing. It contends that Dr. Bercu's opinions are unreliable because he did not personally examine Plaintiff or rely on any "guidelines in the field of endocrinology." This objection goes to the weight, not the admissibility of Dr. Bercu's opinion about the cause of Plaintiff's medical condition. Defendant does not explain how an in-person examination of Plaintiff is medically relevant to assessing etiology or what guidelines Dr. Bercu should have -- but did not -- consult in forming his opinion.

Defendant also argues that Dr. Bercu's opinion is unreliable because he did not consider the entirety of Plaintiff's medical history. In support, Defendant cites the portion of Dr. Bercu's deposition in which he was asked if he would be "surprised" to learn that the records for March 4 through 10, 2014, from the Bronx Lebanon Hospital were not "a complete set." Even assuming the records from one week in 2014 were incomplete, this does not render Dr. Bercu's testimony inadmissible. Defendant does not identify which records Dr. Bercu failed to review or how they undermine his opinions.

Defendant also cites cases in which summary judgment was granted in its favor as to Risperdal-related claims or the plaintiffs' medical experts were precluded. These cases are inapposite as they involve different facts. *See, e.g., Coleson v. Janssen Pharm., Inc.*, No. 15 Civ. 4792, 2017 WL 1745508, at *6 (S.D.N.Y. May 3, 2017) (pro se plaintiff, who did not develop gynecomastia until five years after ingesting Risperal, lacked any expert testimony on issue of

causation); *Lawson v. Janssen Pharm., Inc.*, No. 15 Civ. 512, 2016 WL 8716480, at *2 (W.D. La. Dec. 16, 2016) (testimony of plaintiff’s expert inadmissible because he failed to refer to any scientific literature, exclude other potential causes or consider medical records that revealed “no indication of enlarged breast[s] much less gynecomastia”); *Williams v. Janssen Pharm., Inc.*, No. 14 Civ. 3354, 2016 WL 6127526, at *3 (W.D. La. Oct. 20, 2016) (plaintiff did not adduce any expert testimony); *Brown v. Johnson & Johnson Pharm.*, No. 12 Civ. 1381, 2015 WL 235135, at *4 (D. Conn. Jan. 16, 2015) (same). Defendant ignores that other courts have found triable issues of fact as to whether Risperdal caused a plaintiff’s gynecomastia. *See, e.g., Schilling v. Ellis Hosp.*, 906 N.Y.S.2d 187, 189 (3d Dep’t 2010).¹

Defendant’s motion to preclude Plaintiff’s medical causation expert is denied. Accordingly, the motion for summary judgment is denied to the extent Defendant contends that Plaintiff lacks admissible expert testimony with respect to general and specific causation.

III. SUMMARY JUDGMENT

Summary judgment is appropriate where the record before the court establishes that there is no “genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A genuine dispute as to a material fact exists “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The court must construe the evidence in the light most favorable to the nonmoving party and must draw all reasonable inferences in favor of the

¹ “According to an online news report, there are currently more than 5,500 lawsuits pending in the Complex Litigation Center of the Philadelphia Court of Common Pleas alleging injuries arising out of the use of Risperdal. The cases generally allege that Risperdal use caused boys and young men to undergo gynecomastia, a condition in which a male develops female breast tissue. As of April 10, 2017, eight of the cases had gone to trial with verdicts evenly split between defendants and plaintiffs, including a \$77 million plaintiff’s verdict in one case.” *Cole v. Janssen Pharm., Inc.*, No. 15 Civ. 57, 2017 WL 3044642, at *1 (E.D. Wis. July 13, 2017)).

nonmoving party. *See id.* at 255. When the movant has properly supported its motion with evidentiary materials, the opposing party must establish a genuine issue of fact by “citing to particular parts of materials in the record.” Fed. R. Civ. P. 56(c)(1)(A). “[A] party may not rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment.” *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) (alteration in original) (internal quotation marks omitted).

A. Breach of Warranty Claims

Defendant argues that the breach of implied warranty claim fails because Plaintiff does not adduce evidence of causation. *See Caccese*, 53 N.Y.S.3d at 61; *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 627 (S.D.N.Y. 2012) (applying New York law). Because, as explained, Plaintiff has raised a factual dispute on this issue, summary judgment is denied on this basis.² Defendant’s contention that Plaintiff abandoned this claim by failing to respond to Defendant’s argument in his opposition is incorrect. While Plaintiff did not expressly refer to the implied warranty claim, he responded to the substance of Defendant’s argument, contending that a factual dispute as to the cause of Plaintiff’s gynecomastia exists.

Summary judgment is granted on Plaintiff’s express warranty claim. Plaintiff fails to identify any misleading “affirmation of fact or promise” from Defendant that induced Plaintiff’s Risperdal use. *Schimmenti v. Ply Gem Indus., Inc.*, 156 A.D.2d 658, 659 (N.Y. 1989) (internal quotation marks omitted); *see, e.g., Meyer v. Alex Lyon & Son Sales Managers & Auctioneers*,

² The dismissal of the failure-to-warn claim, as discussed below, does not preclude the implied warranty claim. *See Denny v. Ford Motor Co.*, 662 N.E.2d 730, 739 (N.Y. 1995) (observing that “causes of action for strict products liability [which includes failure-to-warn] and breach of implied warranty of merchantability are not identical in New York”).

Inc., 889 N.Y.S.2d 166, 168 (1st Dep’t 2009) (plaintiff’s claim dismissed in absence of evidence regarding reliance).

B. Failure to Warn Claim

Summary judgment is granted to the extent Plaintiff’s claims are predicated on an alleged failure to warn. Under New York law, “failure-to-warn claims grounded in strict liability and negligence are functionally equivalent.” *In re N.Y.C. Asbestos Litig.*, 59 N.E.3d 458, 469 (N.Y. 2016). To prevail on such a claim, plaintiff must prove that “(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm.” *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App’x 8, 10 (2d Cir. 2011) (summary order) (citing *Liriano v. Hobart Corp.*, 700 N.E.2d 303, 305 (N.Y. 1998)).

New York courts apply the “learned intermediary doctrine” to failure-to-warn claims based on prescription drugs. *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999); *accord Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993). This requires a defendant to “giv[e] adequate warning to the prescribing physician” who “must then balance the risks and benefits of various drugs and treatments and act as an ‘informed intermediary’ between manufacturer and patient.” *Spensieri*, 723 N.E.2d at 549 (quoting *Martin*, 628 N.E.2d at 1311).

To determine whether “[a] warning for a prescription drug may be held adequate as a matter of law . . . or presents a factual question,” a court must assess “whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug.” *Martin*, 628 N.E.2d at 1312. “The adequacy of the instruction or warning is generally a question of fact to be determined at trial and is not ordinarily susceptible

to the drastic remedy of summary judgment.” *Urena v. Biro Mfg. Co.*, 114 F.3d 359, 366 (2d Cir. 1997) (quoting *Beyrle v. Finneron*, 606 N.Y.S.2d 465, 466 (4th Dep’t 1993)).

Even assuming -- without deciding -- that there is a factual dispute as to the adequacy of the label, Plaintiff’s claim fails because there is no evidence from which a reasonable jury could conclude that any failure to warn caused Plaintiff’s injuries. Plaintiff’s sole argument is that the law “presume[s] that a user would have heeded warnings if they had been provided, and that the injury would not have occurred,” *Roman v. Sprint Nextel Corp.*, No. 12 Civ. 276, 2014 WL 5026093, at *13 (S.D.N.Y. Sept. 29, 2014) (quoting *In re Fosamax Prod. Liab. Litig.*, 924 F. Supp. 2d 477, 486 (S.D.N.Y. 2013)), and that this presumption alone defeats summary judgment.

Plaintiff incorrectly invokes this so-called “heeding presumption,” which derives from the assumption that “[w]here warning is given, the seller may reasonably assume that it will be read and heeded[.]” Restatement (Second) of Torts § 402A cmt. j (1965). However, “[f]ailure-to-warn liability is intensely fact-specific, including but not limited to such issues as . . . proximate cause.” *Liriano*, 700 N.E.2d at 309. Particularly in a case involving failure to warn of the risks of a pharmaceutical product, depending on the plaintiff’s condition and treatment alternatives, one may not reasonably assume that a patient or his treating physician will forego a drug because of disclosed risks. The New York Court of Appeals, in response to defendant’s argument that the trial court should not have instructed the jury on any heeding presumption, observed that “the burden of demonstrating that the injured party would have heeded warnings[] falls squarely on plaintiffs.” *In re N.Y.C. Asbestos Litig.*, 59 N.E.3d at 482 (refusing to address whether the jury instruction on the heeding presumption was proper because defendant had failed to preserve the issue for appeal) (citing, e.g., *Sosna v. Am. Home Prod.*, 748 N.Y.S.2d 548 (1st Dep’t 2002)). In *Sosna*, the First Department affirmed the dismissal of the case on summary

judgment and held, “[I]t remains plaintiff’s burden to prove that defendant’s failure to warn was a proximate cause of his injury . . . and this burden includes adducing proof that the user of a product would have read and heeded a warning had one been given.” 748 N.Y.S.2d at 549; accord *Reis v. Volvo Cars of N. Am., Inc.*, 73 A.D.3d 420, 423 (1st Dep’t 2010) (reversing denial of summary judgment “because there is no evidence that any such failure [to warn] was a proximate cause of the injury”). The Second Circuit similarly summarized New York law, stating “a plaintiff is not entitled to a [heeding] presumption,” and “[u]ltimately, the issue is whether the facts and circumstances presented by the plaintiff in a particular case permit a jury reasonably to infer that a warning, reasonably required, would have been heeded.” *Raney v. Owens-Ill., Inc.*, 897 F.2d 94, 96 (2d Cir. 1990).

Here, no reasonable jury could conclude that any failure to warn caused Plaintiff’s injuries. Plaintiff cites no direct evidence, such as the testimony from his doctors, that Plaintiff would not have been prescribed Risperdal in the same manner if the warning were more extensive. Cf. *In re N.Y.C. Asbestos Litig.*, 59 N.E.3d at 481 (finding plaintiff carried her burden to prove failure to warn was proximate cause where the decedent testified he would have “read and heeded any warnings”). Nor does Plaintiff adduce any evidence suggesting that a physician balancing the risks of Risperdal-induced gynecomastia against the benefits of Risperdal would conclude that Risperdal should not have been prescribed to Plaintiff. See *Martin*, 628 N.E.2d at 1311 (noting the duty of physicians “to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects”). Plaintiff cannot rely on mere speculation as to this medical determination to defeat summary judgment.

The evidence that does exist, even when construed in Plaintiff’s favor, confirms that Plaintiff’s causation theory is inadequate. Plaintiff has been prescribed Risperdal or risperidone

three times over the course of the decade, including after the 2006 label strengthened the warnings with respect to gynecomastia. Plaintiff also offers nothing to rebut the affidavit from Dr. Harvey Hammer, a child psychiatrist Defendant retained as an expert. Dr. Hammer attests that he has prescribed Risperdal for over 100 children and adolescents and found it to be “safe and effective” for multiple psychiatric disorders. He also attests that, since the 1990s, “Child psychiatrists were aware of the possible risks associated with second-generation antipsychotics,” such as Risperdal, including the relationship between Risperdal and gynecomastia. *Raney*, 897 F.2d at 96 (absence of a warning not a proximate cause if the plaintiff had “the same awareness of danger as [if] the warning would have given”).

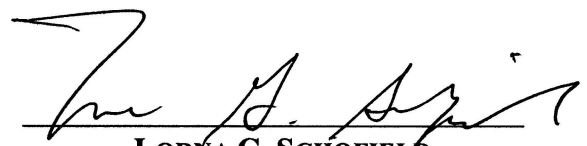
Summary judgment is granted on the failure-to-warn claims because Plaintiff adduces no evidence from which a reasonable jury could conclude that his treating physicians would not have prescribed Risperdal in the same manner if the label had more extensively identified the risks of developing gynecomastia. *See, e.g., McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 408 (S.D.N.Y. 2014) (applying New York law; “[s]ummary judgment is appropriate where a plaintiff fails to establish that a prescribing physician’s decision to prescribe a particular medication would have changed had a different warning been given.”).

IV. CONCLUSION

For the foregoing reasons, Defendant’s motion to preclude is DENIED and motion for summary judgment is GRANTED as to the express warranty claim and the failure-to-warn claims, but DENIED in all other respects. Defendant’s request for oral argument is DENIED as moot.

The Clerk of Court is respectfully directed to close the motion at Dkt. Nos. 56 and 57.

Dated: August 30, 2017
New York, New York


LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE